

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: James FULLER  
Title: NUCLEIC ACID CONSTRUCTS  
Appl. No.: 10/575,087  
Filing Date: April 10, 2006  
Examiner: Unassigned  
Art Unit: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits. Therefore, no fee is due.

**RELEVANCE OF EACH DOCUMENT**

Documents B1-B48 were found during a search of the files of the present application and related patent applications. All documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicants believe that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date Feb 13, 2007

By Michael M. Peet  
Reg No. 34,717

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**INFORMATION DISCLOSURE  
 STATEMENT BY APPLICANT**

Date Submitted: February 15, 2007

(use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number 10/575,087  
 Filing Date April 10, 2006  
 First Named Inventor James FULLER  
 Art Unit Unassigned  
 Examiner Name Unassigned  
 Attorney Docket Number 036481-0177

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	B1	5,100,792	03/31/1992	SANFORD et al.	
	B2	5,168,062	12/01/1992	STINSKI	
	B3	5,385,839	01/31/1995	STINSKI	
	B4	5,630,796	05/20/1997	BELLHOUSE et al.	
	B5	5,865,796	02/02/1999	MCCABE	
	B6	6,110,707	08/29/2000	NEWGARD et al.	
	B7	6,218,140	04/17/2001	FLECKENSTEIN et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	B8	CA 2,425,852 A	04/18/2002	CHIRON CORPORATION		
	B9	EP 0323997 B1	07/19/1989	CELLTECH LIMITED		
	B10	WO 95/020660	08/03/1995	UNIV. OF MASSACHUSETTS MEDICAL CENTER		
	B11	WO 99/003981	01/28/1999	PPL THERAPEUTICS		
	B12	WO 99/061472	12/02/1999	VALENTIS, INC.		
	B13	WO 00/023592	04/27/2000	POWDERJECT VACCINES, INC.		
	B14	WO 01/058483 A2	08/16/2001	THE UNIVERSITY OF VIRGINIA PATENT FOUNDATION		
	B15	WO 02/031137 A2	04/18/2002	CHIRON CORPORATION		
	B16	WO 02/036792 A2	05/10/2002	GLAXO GROUP LIMITED		
	B17	WO 02/094313 A2	11/28/2002	POWDERJECT VACCINES, INC. and POWDERJECT RESEARCH LIMITED		
	B18	WO 03/011334 A1	02/13/2003	GLAXOSMITHKLINE BIOLOGICALS S.A. and GLAXO GROUP LIMITED		
	B19	WO 03/004055 A2	01/16/2003	POWDERJECT VACCINES, INC.		
	B20	WO 05/035779 A2	04/21/2005	POWDERJECT VACCINES, INC.		
	B21	WO 06/082398 A2	08/26/2006	POWDERJECT VACCINES, INC. and POWDERMED LIMITED		

Examiner  
Signature

Date  
Considered

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Substitute for form 1449/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<b>Application Number</b>	10/575,087
Date Submitted: February 15, 2007			<b>Filing Date</b>	April 10, 2006
(use as many sheets as necessary)			<b>First Named Inventor</b>	James FULLER
			<b>Art Unit</b>	Unassigned
			<b>Examiner Name</b>	Unassigned
<b>Sheet</b>	2	of 4	<b>Attorney Docket Number</b>	036481-0177

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	B22	ARRINGTON et al., "Plasmid Vectors Encoding Cholera Toxin or the Heat-Labile Enterotoxin from <i>Escherichia coli</i> Are Strong Adjuvants for DNA Vaccines," <i>Journal Of Virology</i> , May 2002, pp. 4536-4546, vol. 76, no. 9, [XP-002379962].	
	B23	BANERJI et al., "Expression of a $\beta$ -Globin Gene Is Enhanced by Remote SV40 DNA Sequences," <i>Cell</i> , Dec. 1981 (Part 1), pp. 299-208, vol. 27.	
	B24	BARDIYA et al., "Influenza Vaccines: Recent Advances in Production Technologies," <i>Appl Microbiol Biotechnol</i> , 2005, pp. 299-305, vol. 67, no. 3 [XP-002379964].	
	B25	CHAN et al., "Synergistic Interactions between Overlapping Binding Sites for the Serum Response Factor and ELK-1 Proteins Mediate both Basal Enhancement and Phorbol Ester Responsiveness of Primate Cytomegalovirus Major Immediate-Early Promoters in Monocyte and T-Lymphocyte Cell Types," <i>Journal Of Virology</i> , Dec. 1996, pp. 8590-8605, vol. 70, no. 12 [XP-002331463].	
	B26	CHAPMAN et al., "Effect of Intron A from Human Cytomegalovirus (Towne) Immediate-Early Gene on Heterologous Expression in Mammalian Cells," <i>Nucleic Acids Research</i> , 1991, pp. 3979-3986, vol. 19, no. 14, Oxford University Press.	
	B27	deVILLIERS et al., "A Small Segment of Polyoma Virus DNA Enhances the Expression of a Cloned $\beta$ -Globin Gene over a Distance of 1400 Base Pairs," <i>Nucleic Acids Research</i> , 1981, pp. 6251-6264, vol. 9, no. 23.	
	B28	DONNELLY et al., "Preclinical Efficacy of a Prototype DNA Vaccine: Enhanced Protection Against Antigenic Drift in Influenza Virus," <i>Nature Medicine</i> , June 1995, pp. 583-587, vol. 1, no. 6 [XP 000508527].	
	B29	FULLER et al., "Immune Responses to Hepatitis B Virus Surface and Core Antigens in Mice, Monkeys, and Pigs after Accell <sup>®</sup> Particle-Mediated DNA Immunization," <i>Annals New York Academy of Sciences</i> , 1995, pp. 282-284, vol. 772, no. 27 [XP-000891484].	
	B30	GARMORY et al., "DNA Vaccines: Improving Expression of Antigens," <i>Genetic Vaccines and Therapy</i> , 2003, pp. 1-5, vol. 1, no. 2 [XP-002379963].	
	B31	HAENSLER et al., "Intradermal DNA Immunization by Using Jet-Injections in Mice and Monkeys," <i>Vaccine</i> , 1999, pp. 628-638, vol. 17, nos. 7-8.	
	B32	HEARING et al., "The Adenovirus Type 5 E1A Transcriptional Control Region Contains a Duplicated Enhancer Element," <i>Cell</i> , July 1983, pp. 695-703, vol. 33.	
	B33	KUTINOVA et al., "Hepatitis B virus proteins expressed by recombinant vaccinia viruses: influence of preS2 sequence on expression surface and nucleocapsid proteins in human diploid cells," <i>Archives of Virology</i> , 1994, pp. 1-15, vol. 134.	

<b>Examiner Signature</b>	<b>Date Considered</b>
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Sheet 3 of 4

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Filing Date	April 10, 2006
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Examiner Name	Unassigned
Attorney Docket Number	036481-0177

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Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>§</sup>
	B34	LEE et al., "Development of a Polynucleotide Vaccine from Melanoma Antigen Recognized by T Cells-1 and Recombinant Protein from Melanoma Antigen Recognized by T Cells-1 for Melanoma Vaccine Clinical Trials," <u>Journal of Immunotherapy</u> , 2000, pp. 379-386, vol. 23, no. 3.	
	B35	LEVINSON et al., "Activation of SV40 genome by 72-base pair tandem repeats of Moloney sarcoma virus," <u>Nature</u> , Feb. 1982, pp. 568-5721, vol. 295.	
	B36	LÖSER et al., "Evaluation of HBV Promoters for Use in Hepatic Gene Therapy," <u>Biol Chem.</u> , Mar. 1996, pp. 187-193, vol. 377.	
	B37	LUCIW et al., "Location and Function of Retroviral and SV40 Sequences That Enhance Biochemical Transformation after Microinjection of DNA," <u>Cell</u> , Jul. 1983, pp. 705-716, vol. 33.	
	B38	MASUDA et al., "Effect of the PreS1 RNA Sequence on the Efficiency of the Hepatitis B Virus PreS2 and S Protein Translation," <u>Virology</u> , 1990, pp. 320-324, vol. 174.	
	B39	MONTGOMERY et al., "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors," <u>DNA And Cell Biology</u> , 1993, pp. 777-783, vol. 12, no. 9 [XP 000565708].	
	B40	ROSENTHAL et al., "BK Viral Enhancer Element and a Human Cellular Homolog," <u>Science</u> , 1983, pp. 749-755, vol. 222.	
	B41	ROTONDARO et al., "Efficiency of different viral promoters in directing gene expression in mammalian cells: effect of 3'-untranslated sequences," <u>Gene</u> , 1996, pp. 195-198, vol. 168, no. 2.	
	B42	ROY et al., "Induction of antigen-specific CD8 + T cells, T helper cells, and protective levels of antibody in humans by particle-mediated administration of a hepatitis B virus DNA vaccine," <u>Vaccine</u> , 2001, pp. 764-778, vol. 19.	
	B43	SIMARI et al., "Improved transgene expression in vascular smooth muscle cells using downstream sequences from the CMV IE gene," <u>Circulation</u> , Supplement 1, Oct. 15, 1996, p. 1-44, vol. 94, no. 8.	
	B44	SIMONSEN et al., "Analysis of Processing and Polyadenylation Signals of the Hepatitis B Virus Surface Antigen Gene by Using Simian Virus 40-Hepatitis B Virus Chimeric Plasmids," <u>Molecular And Cellular Biology</u> , Dec. 1983, pp. 2250-2258, vol. 3, no. 12.	
	B45	WASENAUER et al., "A Cysteine and a Hydrophobic Sequence in the Noncleaved Portion of the Pre-C Leader Peptide Determine the Biophysical Properties of the Secretory Core Protein (HBe Protein) of Human hepatitis B Virus," <u>Journal Of Virology</u> , Sep. 1992, pp. 5338-5346, vol. 66, no. 9 [XP-002977293].	
	B46	WEEKS et al., "E1A Control of Gene Expression Is Mediated by Sequences 5' to the Transcriptional Starts of the Early Viral Genes," <u>Molecular And Cellular Biology</u> , Jul. 1983, pp. 1222-1234, vol. 3.	

Examiner  
SignatureDate  
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		<b>Attorney Docket Number</b>	036481-0177
Sheet	4	of	4

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	B47	YANG et al., "Particle Bombardment Technology for Gene Transfer (1994)," Oxford University Press, New York, NY, 1994, pp. 10-11.	
	B48	ZINCKGRAF et al., "Modulating gene expression using DNA vaccines with different 3'-UTRs influences antibody titer, seroconversion and cytokine profiles," <u>Vaccine</u> , 2003, pp. 1640-1649, vol. 21, no. 15.	

Examiner Signature	/Michelle Horning/	Date Considered	09/07/2010
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